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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/092,095

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Brian Bates

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7590 09/18/2007
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EXAMINER

DAWSON, GLENN K

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

09/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/092,095	BATES, BRIAN	
	Examiner	Art Unit	
	Glenn K. Dawson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-50, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-50, 73, 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-50, 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The original specification does not provide support for a support frame including a non-mesh structure. Also unsupported is the non-mesh structure being formed of one or more frame threads. Each of the figures having more than one frame thread appears to show a mesh. Mesh is defined as an openwork fabric or structure. Since openings are formed within the structure and are bounded by wire portions, the examiner contends that the structures shown are indeed consistent with the commonly known definition of a mesh. Applicant does make specific reference to the invention using mesh stents, but not non-mesh stents. Also disclosed on page 3 of the applicant's specification is that a mesh stent can be formed from a single frame thread. It is unclear what structure applicant intends to cover with the phrase "non-mesh".

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a non-mesh stent

Art Unit: 3731

formed of more than one frame thread, and the thread comprising a full circle must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. It would appear that each of the stents shown which have more than one frame thread would meet the definition of a mesh. A full circle has no beginning or end. It lies within a single plane. Each of the figures and the description of the invention leads one to believe that the rings are not full circles as they are coils, but since the coils are open and are not continuous, they do not form a full circle.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3731

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-50, 73 and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what type of structure applicant intends to cover with the phrase "non-mesh stent".

The use of the term "thereabout" is unclear as it is not clear what claimed structure the threads are wrapped about.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-48,50,73, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,080,191 to Summers in view of US Patent No. 6,245,100 to Davila et al., and further in view of US Patent No. 5,951,599 to McCrory.

Summers discloses several stent patterns in Figures 1-5 and 21 that meet many limitations of the claims. The embodiment of the stent in Figures 1-5 is formed from a single wire (column 3, line 65), has ring segments joined by curved regions, and adjacent rings are interleaved. The embodiment in Figure 21 has a longitudinal support and is formed from a flat sheet of material.

Summers states that a graft material may be attached to any of the disclosed stent frames to seal an aneurysm (column 11, lines 25-52), but Summers fails to disclose the specific means of attaching the graft to the stent frame.

The limitation "secured to said support frame by folding one end of said graft material around one of said frame threads..., and connecting two layers..." is a

Art Unit: 3731

product by process limitation. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. The prior art only needs to meet the structural requirements - the graft only needs to encapsulate the frame threads at the end of the stent and have an area of double thickness. Davila et al. discloses another stent-graft and teaches that it advantageous to fix a graft to a stent by folding the ends over the stent frame and attaching the layers to one another, as this attachment ensures that the graft will not move relative to the stent during further assembly and implantation {column 9, lines 38-50}. It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the graft of Summers by folding the ends over the frame and bonding the layers together, as Davila teaches that this helps to prevent shifting of the graft during further assembly processes and delivery. Summers and Davila fail to state that the graft material only covers a portion of the stent circumference. McCrory discloses another stent frame with a graft attached to it. As shown in Figure 2A, the graft (22) extends only a portion of the length and circumference of the frame. The graft extends at least 1/4 of the circumference. The graft material is an impermeable polymer that is attached to the frame by various attachment means including woven, glued or any other suitable attachment mechanism (column 4, lines 14-19) and is intended

for sealing an aneurysm. The examiner contends that suturing would be an obvious alternative to weaving or adhesive. McCrory teaches that this particular configuration of the graft material allows the blood to flow through the apertures of the stent except at the neck of the aneurysm, where thrombosis is desired (column 3, lines 1-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a partial circumference graft on the modified Summers stent frame, as McCrory teaches that this configuration allows blood to flow through the stent frame apertures except at the site of the aneurysm sac. This configuration effectively seals the aneurysm without significantly affecting the flow of blood to other areas of the vessel.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Summers in view of Davila and McCrory, as applied above, and further in view of US Patent App. Pub. No. 2003/0139802 (Wulfman et al.).

The modified Summers device makes obvious the invention as claimed with the exception of failing to configure the partial circumference graft to extend the full length of the stent. Wulfman discloses another stent frame that

Art Unit: 3731

includes a graft (28) is disposed over approximately half of the circumference of the frame (26). Similar to McCrory, the graft material (28) is also an impermeable polymer material that is attached to the frame by various attachment means (0033). Wulfman teaches that a partial circumference graft can extend the full length of the stent as an alternative to a partial length of the stent [0029]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the graft of the modified Summers device to extend the full length of the stent, as Wulfman teaches that this simple modification allows the device to be adapted for various types of vessel irregularities.

Response to Arguments

Applicant's arguments filed 04-23-2007 have been fully considered but they are not persuasive.

Applicant argues that Davilla does not disclose a partially coated stent and that several of the references disclose stents with different structure than that of the applicant, and that Davila is not a mesh structure like McCrory. Applicant argues that Davilla's graft is attached only over the outer stent of two nested stents, and there is no suggestion that Davilla could be used for a partially coated stent graft or that it could be used with the claimed stent structure. Finally, the references do not relate to the claimed invention.

Applicant appears to be arguing the references individually instead of arguing the combination.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Summers discloses stent's with the exact same structure disclosed and claimed by the applicant. However, the manner of attachment of the graft to the stent is not specified. One skilled in the art looking for possible ways of attaching a graft to a stent would look to any stent/graft combination for possible solutions. The fact that Davilla teaches of wrapping a stent around frame threads of just an outer stent of a nested stent structure still provides a teaching of how to attach a graft to one stent. The teaching of wrapping the ends of the graft around the ends of the frame threads would be perfectly combinable with the stent of Summers. McCrory teaches that a stent/graft combination can be used to seal aneurysms and teaches of only attaching the graft to a portion of the circumference of the stent. The type of stent would appear to be irrelevant. Both stents of Summers and McCrory appear to have a common intended use to treat aneurysms. Therefore, the combination of the three references would place a graft folded over the frame threads of a stent only over a portion of the circumference

of the stent. The addition of Wulfman would teach extending the graft over the entire length of the stent in order to adapt to various vessel irregularities.

The examiner contends that such a combination is not based on improper hindsight reconstruction.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Only knowledge gleaned from the cited references is necessary to be motivated to make the proposed combination which reads on all of the claimed limitations.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone

Art Unit: 3731

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Glen K Dawson
Primary Examiner
Art Unit 3731

Gkd
12 September 2007